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HALO® Fact Sheet

Key Facts

- 1 in 8 women will develop breast cancer in her lifetime
- 70 % of women diagnosed with breast cancer have **no identifiable risk factors**
- 8 in 9 women diagnosed with breast cancer have **no family history**
- Breast cancer in younger women is typically more aggressive with worse outcomes.
- A lump has typically been growing for more than 8 years by the time it is seen on a mammogram
- With early diagnosis, the 5-year survival rate for breast cancer is nearly 100%

What is the HALO Breast Pap Test?

HALO is a risk assessment tool that helps determine a woman's individual risk of developing breast cancer.

HALO is the only fully automated, noninvasive system used to assess a woman's individual risk for developing breast cancer. HALO is FDA-cleared for the collection of nipple aspirate fluid (NAF) for cytological evaluation. Designed for women 25 and older, the simple, 5-minute test is well tolerated and is included as part of the annual well-woman visit in a physician's office.

The lab fees for NAF evaluation are typically reimbursed by most insurance companies because this is not a new procedure. The HALO sample collection process is not typically reimbursed because it is new. With most new technologies it takes about two years to gain reimbursement. Sample collection costs approximately \$100.

HALO is *NOT*:

- **Ductal lavage**

Unlike ductal lavage -- which requires needles and catheters to be inserted into the nipple -- HALO collects NAF in a quick, non-invasive way using warmth, massage and suction, similar to a breast pump.

- **Diagnostic**

HALO is not intended to diagnose breast cancer. It is a risk assessment tool that helps identify women with precancerous changes who have a high risk of developing breast cancer.

- **A replacement for mammography**

HALO does not take the place of routine mammography and breast exams. All women, regardless of their risk assessment, should undergo routine screening as recommended by their healthcare providers.

How HALO Works

- 1) Adjustable cups are fitted to the woman's breasts
- 2) The system automatically warms the breasts, massages them and applies suction to bring nipple aspirate fluid to the surface.
- 3) If fluid is produced, it is sent to a cytology laboratory for analysis.

Why assess risk?

- Breast cancer is a major health concern and most women want to be proactive about their breast health.
- Similar to the Pap test for cervical cancer, HALO monitors changes in cells to assess the risk for developing breast cancer.
- Thanks largely to the Pap test, deaths from cervical cancer have dropped more than 80% over the past 50 years.

- Risk assessment is a proven part of health improvement. For example, assessing an individual's risk of heart attack by monitoring hypertension and cholesterol levels is a standard practice that can improve cardiac health.
- There are ways to reduce risk for women with atypical cells in their breast ducts, and to monitor them more closely so that breast cancer can be detected at the earliest possible stage if it does develop.

Science Behind HALO

The science behind HALO is not new. Fifty years of research have confirmed the ability to detect early cellular changes through the analysis of NAF and to use NAF to identify high-risk women, but until now, there has been no practical way to collect NAF. HALO provides the opportunity for women and their doctors to at last take advantage of this science in an easy, proven process that provides personalized risk assessment. It enables women to be proactive about their breast health and opens the possibility of preventing breast cancer.

- In 1958, a study by Dr. George Papanicolaou, inventor of the Pap test for cervical cancer, demonstrated the ability to find abnormal cells in NAF from within the breast duct.
- Like the Pap test for cervical cancer, NAF is evaluated for cellular changes at the earliest stage of development.
- Since Papanicolaou's early work, multiple studies involving over 20,000 women followed for up to 25 years have concluded that women with abnormal cells in their breast ducts are 4- to 5-fold more likely to develop breast cancer.

Key Research

- In their recent paper, West and Hollingsworth acknowledged that while premenopausal women with atypia in NAF have a four- to five-times-greater chance of developing breast cancer, physicians often lack a practical way to apply this knowledge. This paper points to HALO as providing a simple, non-invasive, office-based method for collecting NAF in the primary care setting. *Expert Review of Obstetrics and Gynecology, 2008*
- Wrensch and Petrakis, et al. conducted the first prospective study of breast cancer risk using NAF cytological evaluation. The 18-year study involved 2,701 women with an average of more than 12 years of follow-up. The results indicated that atypical hyperplasia found in NAF is associated with a 4.9-fold increased risk of breast cancer. *American Journal of Epidemiology, 1992*

- A study by DuPont and Page followed 3,303 women for a median of 17 years to assess the impact of various breast cancer risk factors in women with benign proliferative breast disease. The study showed that the presence of atypical hyperplasia indicated a 4.3-fold elevated risk of developing breast cancer. *Cancer, 1993*
- In a prospective study, Fabian et al. of the University of Kansas Medical Center followed 480 high-risk women over 10 years to determine if the presence of epithelial cells in NAF was associated with later breast cancer development. Researchers found that atypical cells in nipple aspirates increases the relative risk by a factor of 5.02. *Journal of the National Cancer Institute, 2000*
- In one of the largest studies of its kind, Hartmann et al. examined the relative risk of breast cancer associated with benign breast disease (such as atypical hyperplasia, which can be detected by NAF assessment). The long-term study followed 9,087 women for a median of 15 years. This study found that atypical cells indicate a 4.24 relative risk of developing breast cancer. *New England Journal of Medicine, 2005*
- A study of 500 women by Proctor et al. of the University of Utah, Department of Pathology, concluded that HALO is a simple, safe, automated method for standardized collection of NAF that is well-tolerated by women. The major advantage of HALO, the authors reported, is that it is automatic and easy to use, which removes clinician variability and ensures a safe, consistent NAF screening. It is also less invasive than either ductal lavage or fine needle aspiration. *Biomed Central Women's Health, 2005*
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